8 PATIENT EXAMINATION GLOVES

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DEFINITION AND STATUTORY AND REGULATORY REQUIREMENTS

Under the proposed rule, patient examination gloves would be Class II (special controls) devices and would be identified as follows:

Patient Examination Gloves, powdered (proposed §880.6250). A powdered patient examination glove is a disposable device made of natural rubber latex or synthetic material that bears powder to facilitate donning and is intended to be worn on the hand or finger(s) for

medical purposes to provide a barrier against potentially infectious materials and other contaminants.

The proposed Class II special controls are:

1. The Center for Devices and Radiological Health, FDA, *Medical Glove Guidance Manual*, revised ?? (date). (this manual)

2. User labeling requirements in 21 CFR §801.440

Patient Examination Gloves, powder-free (proposed §880.6251)**.** A powder-free patient examination glove is a disposable device made of natural rubber latex or synthetic material that may bear a trace amount of glove powder and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

The proposed Class II special controls are:

1. The Center for Devices and Radiological Health, FDA, *Medical Glove Guidance Manual*, as revised.
2. User labeling requirements in 21 CFR §801.440.

Manufacturers of patient examination gloves are subject to the registration, listing, 510(k), labeling, Quality System and Medical Device Reporting (MDR) requirements of the Food, Drug and Cosmetic Act. Variations in patient examination gloves are listed in Table 3.1 in Chapter 3. Manufacturers must receive a 510(k) clearance letter from FDA before distributing medical gloves in the U.S.

Powder used for lubricating examination gloves should meet the United States Pharmacopoeia (U.S.P.) monograph for absorbable dusting powder or be shown to be equivalent in terms of safety and effectiveness. The 510(k) should include the type, specifications and source of powder or other donning lubricant used on the gloves. Talc, cotton flock, and other non-absorbable materials are **not** acceptable as a lubricating, dusting or donning powder. Paragraph 4.3 of ASTM standards D 3578 or D 5250 requires the inside and outside surface of examination gloves to be free of talc. Lycopodium (club moss spores) and ground pine pollen are toxic and are not acceptable as powder on or in medical gloves.

Gloves should be subjected to leaching and washing or other appropriate reduction and removal processes for manufacturing material residue. Note that natural latex proteins are concomitant manufacturing materials as defined in 21 CFR §820.3(p) and must be controlled per §820.70(h).

Biocompatibility data should be submitted for all medical gloves. Because examination gloves are in direct contact with skin, a Primary Skin Irritation study and a Dermal Sensitization Study are appropriate. [See FDA CDRH ODE Blue Book G95-1, ISO TC

10993, and Chapter 5 for further guidance.] Biocompatibility tests should be performed on finished gloves. The data should be fully identified and presented in tables when feasible.

When a study such as a biocompatibility study is conducted by an internal or contract laboratory to establish a specification and/or obtain data for a submission to FDA, the device manufacturer should keep the **original** record of the results of the study on file at their factory or other readily accessible location. This original document should also include the name and address of the laboratory and device manufacturer; the device identity; and dates of testing.

If a change is made to gloves that could significantly affect safety or effectiveness, such as adding or deleting powder; adding color, fragrance or a claim to the labeling; or modifying an important process, a new and **complete** 510(k) should be submitted. A new 510(k) usually is not required if a manufacturer only does more of an existing process such as extra leaching or washing and makes no claim or mention of this change on the product labeling. A 510(k) submission for a new glove or for a modification to an existing glove may also be submitted according to the guidance titled, *"The New 510(k) Paradigm - Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,"* available on the World Wide Web at:
http://www.fda.gov/cdrh/ode/parad510.pdf.

The submitter of a 510(k) for a modified glove should reference the original 510(k) number. Changes to patient examination gloves, labeling, packaging, processes, etc., are to be made according to the Quality System Regulation at 21 CFR §§820.40 and 820.70(b). FDA is proposing that patient examination gloves be reclassified as Class II devices. If patient examination gloves become Class II, changes to them must also meet the design control requirements of §820.30. [Changes made to documents under §820.30 automatically meet the requirements in §820.40.]

VOLUNTARY STANDARDS

FDA relies on the voluntary standards issued by the American Society for Testing and Materials (ASTM) D 3578, D 3772 (finger cots) and D 5250 in assessing the parameters of patient examination gloves. ASTM D 5712 covers the *Standard Test Method for the Analysis of Protein in Natural Rubber and Its Products*. (Please see Chapter 12 on *Voluntary Standards*.)

BIOBURDEN AND MOISTURE

The combination of microorganisms, starch, and moisture on examination gloves may result in microbial growth sufficient to cause discoloration, unpleasant odor and, occasionally, dangerous healthcare situations. (Bioburden and moisture control are primarily Quality System topics. However, because of the proposed requirement for expiration dating in §801.440(d) and problems with contaminated examination gloves, this control information is also printed here.)

To keep bioburden levels low on gloves:

- the packaging, donning powder, and gloves should be kept clean throughout storage;
- all manufacturing, handling, and packaging operations should be appropriately controlled;
- spilled coagulant solution and starch slurry or former release agents should be scrupulously cleaned from the floor;
- if post-cure washing is performed, the water or gloves should be monitored and appropriately treated to control microorganisms;
- the starch slurry or other lubricant solution should be cooled, treated with a bactericide, or otherwise controlled to reduce the growth of organisms;
- any air used to cool post-cured gloves should be filtered or otherwise controlled;
- the moisture content of finished gloves should be at or below the manufacturers moisture or dryness specifications; and
- the packaged gloves should be protected from moisture and contamination during storage and shipment.

It is obvious that moist, contaminated gloves cannot meet a significant expiration period or shelf life. Maintaining a long expiration period may require establishing a specification for moisture and bioburden; controlling bioburden; monitoring the moisture content of finished gloves; and ensuring that dispenser boxes be shrink-wrapped with plastic or otherwise be protected from moisture, and other contaminants. Changes in packaging and sealing should be evaluated, validated, and, in general, meet the change control requirements of the QS regulation.

Manufacturers that want to perform tests for bioburden may refer to Association for Advancement of Medical Instrumentation (AAMI) guidelines (USA FAX 703-276-0793) or to IES-RP-CC-005-87-T for *Cleanroom Gloves and Finger Cots* or consult a microbiological test laboratory.

Sterile Examination Gloves

Gloves intended to be sterilized should be controlled as noted above in order to keep their bioburden level well below the level that can be killed by the intended sterilization process.

Information on sterilization is located in Chapter 10 under *Sterilization Notes*. Finished sterile examination gloves should meet the ASTM standards for examination gloves, ASTM D 3578, D 3772, D 5250 or an equivalent standard, as appropriate. The manufacturer should have data demonstrating that the **finished sterile** examination gloves meet all specifications,

including the AQL for pinholes. On a design qualifying basis, the sterilized gloves should pass the manufacturers protein, tensile strength, elongation, thickness, barrier, integrity, pinhole or leak acceptance test AQL, etc., after undergoing real time aging or accelerated aging such as for 7 days at 70 degrees Centigrade as described in ASTM D 3578, ASTM D 5250 or an equivalent standard, as appropriate.

Gloves in Kits

If a manufacturer distributes examination gloves that are intended to be included in medical device kits, where the kit is to be sterilized, then the glove manufacturer should ensure that the gloves are capable of meeting the appropriate ASTM or equivalent glove standard after sterilization. Kit manufacturers and assemblers should be certain that gloves in their kits are cleared for marketing and can meet the appropriate FDA and ASTM or equivalent standards after sterilization by the method being used. Natural rubber latex gloves should be enclosed in their own packaging within the kit to avoid possible protein contamination of other devices. The kit must be labeled, as appropriate, per §801.437 for any latex in the devices or packaging; and eventually labeled per the final version of the proposed §801.440 regulation for the powder and protein on gloves and the expiration date (also see chapter 6).

PREMARKET NOTIFICATION SUBMISSION FORMAT

A suggested format for the submission of a premarket notification [510(k)] for patient examination gloves is presented on the next several pages. It is not a required format; however, it may be used as a guide for submitting the necessary information to FDA. This format will also increase the completeness and accuracy of your submission, and may reduce the time required to clear your gloves for marketing. Guidance for submitting the 510(k) information in this format starts on the next page.

Each 510(k) submission must be for only one type of glove such as a powder-free latex examination glove. Do not mix data for multiple types of gloves in one 510(k) submission. A 510(k) submission must be **complete;** that is, include all of the required information in your submission — do **not** state that the needed information is in another submission.

New 510(k) Paradigm

If examination gloves become Class II as proposed, than a 510(k) submission for a new examination glove or for a modification to an existing examination glove may be submitted according to the guidance titled, *"The New 510(k) Paradigm - Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,"* available on the World Wide Web at:
http://www.fda.gov/cdrh/ode/parad510.pdf.

The applicant may continue to use the following format for applicant information, product identification, and data submissions associated with the new or modified glove. Be

sure to also include the risk analysis, declaration of conformity, etc., as required by the paradigm.

Sample Format for a Premarket Notification [510(K)] for Examination Gloves

Please number the pages in your submission and attachments and include a table of contents. Do NOT include extraneous information such as copies of standards and details of test equipment. Please identify all attachments with the topic and the applicants name, street address, phone and FAX numbers.

1.0 Premarket Notification 510(k) Submission Applicant:
Name

_____

Street Address _____

Country

_____

Phone No. _____ FAX No. _____

_____ A _____
[Registration Number, from Form 2891(a)] (Device Listing Number, from Form 2892)

*(**Registration** is required for all manufacturers, importers, and repackers.*
***Listing** is required by U.S. manufacturers and by foreign manufacturers.*
If the applicant has submitted a registration form but has not received a registration number, enter "applied for" in the registration blank above.)

1.1 Check the activity of the applicant:

[ ] Manufacturer [ ] Repacker [ ] Importer [ ] Consultant [ ] Other

Describe Other:_____
_____
_____

1.2 The applicant **must** include the name of the current manufacturer under 5.0 below. The 510(k) is a permanent record, and the name will not be changed or transferred by FDA.

1.3 Manufacturers that have a contact person within the firm as well as a contact (consultant, importer, etc.) in other locations should give the names of both persons below.

Contact Person in Firm: _____

Phone No. _____ FAX No. _____

Other Contact Person: _____

Phone No. _____ FAX No. _____

2.0 Truthful and Accurate Statement: As shown below, include a statement identifying your capacity or position in the company and the manufacturer's name certifying that all information submitted in the 510(k) is truthful and accurate and that no material fact has been omitted.

Sample

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as (
_____)
The position held in the company

of (_____),
Manufacturer's Name

I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
Signature

_____
Typed Name

_____
Dated

_____
* Premarket Notification 510(k) Number

The statement *must* be signed by a responsible person of the company required to submit the premarket notification — ***not*** a consultant for the submitter.

* For a new submission, do ***not*** fill in the 510(k) number. The Food and Drug Administration will fill in this blank with your 510(k) number when the number is assigned.

3.0 Indications for Use Statement: Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire 510(k) submission must support and agree with the Indications for Use statement.

INDICATIONS FOR USE

Applicant: _____

510(k) Number (if known): ***** _____

Device Name: _____

Indications For Use:

* For a new submission, do **NOT** fill in the 510(k) number.

4.0 Glove Proprietary or Trade Name:

_____

4.1 Modification: If this submission is for a **modification** of an examination glove cleared by FDA for marketing, include the 510(k) number of the cleared glove: _____

5.0 Name and Location of ACTUAL Manufacturer:

Name _____

Address _____

Country _____

Phone No. _____ FAX No. _____

_____ A _____

[Registration Number, from Form 2891(a)] (Device Listing Number, from Form 2892)

6.0 Labels, Labeling, and Advertising: The labeling must include basic information (See Chapter 6 for guidance); and labeling must include the appropriate caution statements and an expiration date as included in proposed §801.440. Include identified copies of all labeling or proposed labeling, including promotional literature. The labeling should contain the common, generic or scientific name of the polymer of which the glove is composed. "Synthetic" used alone has no meaning. If you make any specific claims for your gloves, include data to substantiate the claims in this format or in identified attachments. Puffery, ambiguous, or unsubstantiated claims such as extra thick, low protein, or super sensitive are not allowed. Labeling, labeling claims and data must be consistent with the Indications for Use statement.

7.0 Classification Information

7.1 Device Class: I [Proposed Class II]

7.2 Substantial Equivalent Device Description: (check one)

[ ] Patient Examination Glove, **powdered** 21 CFR 880.6250 proposed

[ ] Patient Examination Glove, **powder-free** 21 CFR 880.6251 proposed

7.3 Product Code: (check one)

[ ] Vinyl - 80LYZ
[ ] Latex - 80LYY
[ ] Synthetic Polymer - 80LZA
[ ] Nitrile - 80LZA
[ ] Specialty - 80LZC
[ ] Finger Cot - 80LZB
[ ] Other - 80FMC

If Finger Cot or “Other,” identify material: _____

_____

8.0 Specifications (of your specific LATEX or Synthetic "xxxx" Polymer Glove (except vinyl):

Overall Length: _____mm minimum

Width: _____mm minimum (for medium glove)

Palm Thickness: _____mm minimum **Finger Thickness:** _____mm minimum

	before aging	after aging
Tensile Strength:	_____ Mpa minimum	_____Mpa minimum
Ultimate Elongation:	_____ % minimum	_____ % minimum
Your Pinhole AQL	_____	_____@70°C for 7 days*

* or equivalent aging to show integrity when used.

Does the above data for your examination gloves meet **ALL** the current specifications listed under the ASTM Specification D 3577.?

YES ___ NO ___ If **NO**, explain why in an identified attachment.

IF VINYL: Your Pinhole AQL before _____ and after aging _____.
Do the vinyl examination gloves meet **ALL** the current specifications listed under ASTM Specification D 5250? **YES ___ NO ___** If NO, explain why in an identified attachment.

8.1 Specialty, Chemotherapy Gloves:

For chemotherapy or other specialty gloves, include in an identified attachment any additional specifications needed to support your labeling claims.

9.0 Quality Assurance Testing (of Finished Gloves):

Finished product quality assurance testing for physical properties such as tensile strength and elongation; dimensions such as length, width, and thickness; chemical tests such as pH; moisture; powder residues; and leak testing are important for assuring a quality product. Visual tests such as color, material uniformity, etc., are also commonly performed. ASTM D 3578, standard for latex examination gloves, and D 5250, standard for vinyl examination gloves, refer to test methods and sampling procedures. For production barrier, integrity, pinhole or leak testing, the sampling and testing should conform to the test methods and AQL established by the manufacturer under their quality system acceptance criteria in 21 CFR 820.181.

Does your quality assurance test results for the examination gloves conform to **ALL** ASTM D 3578, or D 5250 procedures?

YES ____ NO ____

Describe your quality assurance procedures in an identified attachment. The attachment should describe the test methods and acceptance criteria such as sampling procedures, and acceptance quality levels (AQL). Reference any standard test methods that are used.

9.1 Specialty, Chemotherapy Gloves Data:

In addition to the data in 9.0, include data in an identified attachment to show that the gloves are safe and effective for handling chemotherapy agents specified in the labeling or any other special claim.

10.0 Sterility: Are these examination gloves labeled as sterile? YES _____ NO _____

If **YES,** state sterilization method (radiation, gas, etc.) used:_____

10.1 Sterility Assurance Level (SAL): _____

(The SAL is the statistical probability of a glove not being sterile after going through the validated sterilization cycle. The SAL must be 10^{-6} or better for a sterile glove.)

10.2 How was the sterilization cycle validated?

_____

_____

_____

_____

_____

10.3 If Radiation sterilization, dose in Kilograys _____

10.4 If **EtO Sterilization,** level of residue in parts per million (PPM) for:

Ethylene Oxide _____

Ethylene Chlorohydrin _____

Ethylene Glycol _____

10.5 Describe packaging used to maintain sterility: _____

_____

_____

10.6 Sterilizer Name _____

Address _____

Address _____

Country _____

Phone No. _____ FAX No. _____

Registration Number [from Form 2891(a)] _____

If sterilization is done by a contractor, the glove manufacturer must have a contract with the contract sterilizer that meets the requirements of §801.150(e). An importer may need two written agreements: one with the foreign manufacturer; and a second agreement with the contract sterilizer.

11.0 FORMER Release Powder or Chemical: (If none is used, state none and skip to 12.)

Release Powder or Chemical _____

Supplier _____

Specifications _____

12.0 Dusting or Donning Powder: (Skip to 13 if "powder-free")
(ASTM standards do **not** allow Talc on the surface of medical gloves.)

U.S.P. Absorbable Dusting Powder used? YES _____ NO _____.

If **non**-U.S.P. absorbable dusting powder is used, then state the:

Powder Type _____

Supplier _____

Brand Name _____

Specifications _____

_____

12.1 Weight of Donning Powder:

Weight of all types of powder on finished powdered glove _____ +/- _____ milligrams per glove. FDA is recommending that donning powder **not exceed 120 mg per glove.** Powder should be measured by ASTM D-6124, June 24, 1999.

13.0 Weight of Powder-free Residue:

Weight of all types of residual or trace powder on finished powder-free glove _____ +/- _____ mg per glove determined by ASTM D 6124. Residue should **not exceed 2 mg per glove or the limit in the ASTM standard.**

If the gloves are "powder-free," and the process **includes** any mold / former release or donning powder, then the applicant should provide items 13.1 through 13.5 below.

If the gloves are "powder-free" and the process does **NOT** include any powder, then the applicant should complete items 13.4 and 13.5 below.

13.1 Describe the powder(s) introduced at **any** stage of the glove manufacturing process.

_____

_____

13.2 In an identified attachment, describe in detail the process to remove the added powder(s).

13.3 In an identified attachment, include and describe the finished glove release specification supporting the "powder-free" claim and a brief summary of final product testing to ensure finished gloves meet this specification. (You should use the ASTM D 6124 method or an equivalent standard for measuring residual or trace powder.)

13.4 Completely describe in an identified attachment how the glove is designed or manufactured to compensate for the lack of donning powder, or reasons why compensation is not necessary, including a full characterization (e.g., chemical identity, specifications, biocompatibility) of any material such as silicone or polymer coating on the glove to facilitate glove donning.

If a donning lubricant is used, state the exact composition and include **biocompatibility** data for the lubricant in an identified attachment; also state the name, manufacturer, and address below:

Lubricant Generic Name _____

Lubricant Brand Name(s) _____

Lubricant Manufacturer _____

Address _____

_____

Phone No. _____ FAX No. _____

13.5 You should certify that your finished "powder-free" gloves meet ASTM D 3578 standard or equivalent for natural rubber latex or ASTM D 5250 standard or an equivalent standard for vinyl. On a design qualifying basis, the gloves should meet the manufacturers barrier, integrity, pinhole or water leak test and acceptance criteria after being subjected to real time aging or to the ASTM accelerated aging test of 7 days at 70°C. (You may refer to data in 8, 9 and 10 above.)

14.0 Protein Level of Natural Rubber Latex Gloves:

Water soluble protein measured by ASTM D 5712 yielded _____ +/- _____ micrograms per glove. FDA is recommending that protein **should not exceed 1200 micrograms on any size glove.** The sensitivity of ASTM Lowry test method does not support claims below 300 µg per glove (derived from 50µg/gm of glove sensitivity X 6 grams for a typical glove = 300).

14.1 ASTM D 5712-95 *Standard Test Method for the Analysis of Protein in Natural Rubber and Its Products* was used to determine the protein level? YES _____ NO _____

If **NO**, include a complete description of the test method used and data showing how it correlates with the ASTM method.

14.2 The protein testing was performed on the final finished gloves that have undergone real time aging or accelerated aging per ASTM D 3578: YES _____ NO _____

14.3 Include the sampling method and sample size.

14.4 Include your acceptance / rejection criteria.

14.5 Include a summary of test results from samples of at least one lot of gloves using ASTM D 5712-95, that supports your stated protein level.

14.6 Include the chemical identity, biocompatibility, and specification for ANY material added to and remaining on the glove to reduce total water extractable proteins. (You may refer to 18 Biocompatibility below.)

15.0 Protein Control:

In an identified attachment, describe the manufacturing process steps that are used to achieve the protein level.

15.1 In an identified attachment, include a summary of quality control procedures that contains the following 15.2 to 15.6:

15.2 The specification or set point for the glove protein content that will be used for quality control during routine production:

15.3 Specify if a test method **other** than ASTM D 5712-95 will be used for determining protein content during routine production: YES _____ NO _____;

15.4 If 15.3 is YES, include data correlating the routine quality control method to the ASTM D 5712-95 method; and

15.5 Specify the frequency the ASTM D 5712-95 method will be used to verify performance of the routine method. _____

16.0 Chemical Sensitivity Claim: Include your chemical sensitivity claim, if any, in an identified attachment with supporting data. For guidance, please refer to the document titled, *"Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Latex Products,"* available on the World Wide Web at: http://www.fda.gov/cdrh/ode/944.html.

17.0 Color or Flavor Additives:

Any color additive or flavor additive used in manufacturing medical gloves must be identified. Provide the chemical name and composition of the color or flavor additive used. Include in an identified attachment in step 18 biocompatibility data to support safe use of the additive.

18.0 Biocompatibility:

Biocompatibility data should be submitted for examination gloves. Perform biocompatibility tests on finished gloves and include the result in an identified attachment. Use tables where feasible. Because examination gloves contact skin, skin irritation and dermal sensitization tests are considered appropriate.

19.0 Expiration Date or Quality at Delivery:

FDA is proposing that labeling contain an expiration date and, if the proposed regulation becomes final, an expiration date and data to support it will be required in 510(k) submissions. After the proposed regulation becomes a final rule, respond to 19.1; in the interim you should respond to 19.1 or 19.2.

19.1 Expiration Date. For the gloves covered by this 510(k) submission, include the length of the expiration period in months and years in your label claim for which you **have** valid

data to support. [See chapter 6 and proposed §801.440(d) for guidance. Data must be maintained by the manufacturers to support an optional or required (proposed) expiration date of their gloves.]

19.2 Quality at Delivery. If you do not complete 19.1 above, submit data to show that your gloves meet the applicable ASTM or equivalent standard requirements including pinhole requirements after real time aging for at least three months or after accelerated aging for 7 days at 70 degrees centigrade. (No label claim or expiration date is involved or allowed for this minimal data.)

20.0 Other Claims Requiring Data:

List any other claim that needs data to support. _____

_____

_____

20.1 List in a table format the appropriate assay and timeframe for the evaluation that you used for each of the claims in 20.0.

21.0 510(k) Summary/Statement Requirement:

(See Chapter 7, *510(k) Summary and Statement Information*.)

You MUST include on a SEPARATE sheet(s) your name, address and either:

1. a summary of the safety and effectiveness information upon which the substantial equivalence determination is based; OR

2. a statement that the safety and effectiveness information will be made available by your company to the public upon written request.

FDA CLEARANCE LETTER

You may not begin commercial distribution of a device in the United States until you receive a letter from FDA stating that your medical glove was found to be substantially equivalent. Marketing the device prior to a finding of substantial equivalence would render the device adulterated under §501(f)(1)(B) of the FD&C Act and would be subject to enforcement action by the FDA.